

Reconsideration work plan

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|-----------------------------------|---|-------------------------|
| CHEMICAL | Omethoate | |
| REMAINING SCOPE | Residues [5.4], OHS [6.3] | |
| RECONSIDERATION ASSESSMENT PERIOD | 17 months, see Attachment 1 | |
| TIMEFRAME | START: 1 July 2015 | FINISH: 1 December 2016 |
| WORK PLAN DATE | 1 July 2015 updates 12 Nov 2015, 9 March 2016, 4 May 2016 | |

| Stage | Details | Timeline |
|---------------------------------------|---|----------------------------------|
| 1. Nomination | Invitation to nominate agricultural and veterinary chemicals for review – Gazetted on 1 November 1994. | |
| 2. Prioritisation | Omethoate was added to the priority candidate review list of chemicals – Gazetted on 2 May 1995. Scored against agreed selection criteria (public health, OHS, environment and agricultural concerns). | |
| 3. Scoping and work plan | Scope – toxicology, public health, residues and dietary exposure, residues impact on trade and OHS. Link to dimethoate and omethoate scoping document – Published in April 2004. | |
| 4. Notice of reconsideration | s32(1) notices provided to holders (with data requirement) and s32(2) notices sent to States and Territories – 17 March 2004. Link to gazette. s32(2) notices sent to user industry associations on 24 to 26 March 2004 (submissions were due on 2 July 2004) – Published on 6 April 2004. Additional s32 notices sent to holders on 1 July 2015 to include all approved actives and registered products in the review. | |
| START DATE (clock starts) | | 01/07/2015 |
| 5. Assessment | <i>Component assessment reports published</i> Toxicology assessment – Published in November 2011. OHS assessment – Published in November 2015. Residues assessment – Published in March 2016 | |
| 6. Draft regulatory measure | Proposed Regulatory Decisions report – Published 4 May 2016 | Published 4 May 2016 |
| 7. Consultation | The 3-month public consultation period ended 4 August 2016. Submissions made were considered by the APVMA prior to making a final decision. | Ended 4 August 2016 |
| 8. Regulatory decision | The APVMA has: <ul style="list-style-type: none"> Affirmed omethoate active approvals (s34) Varied the instructions for use of products and varied labels and then affirmed them. (s34A) | Completed 1 December 2016 |
| END DATE (regulatory decision) | | 01/12/2016 |
| 9. Implementation | The period for legal supply of product bearing previously approved labels ends 1 December 2017. | |

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Attachment 1

| AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 – S78B | | | |
|---|---|------------------------------|--------------|
| PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RECONSIDERATIONS | | | |
| A + B + 2E + 3C + J + D + X | | | |
| A = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 3.1 | Toxicology – Level 1 | 13 | |
| 3.2 | Toxicology – Level 2 | 9 | |
| 3.3 | Toxicology – Level 3 | 5 | |
| 4.1 | Toxicology (requiring poison schedule classification) | 13 | |
| 7.1 | Environment – Level 1 | 13 | |
| 7.2 | Environment – Level 2 | 7 | |
| 7.3 | Environment – Level 3 | 4 | |
| TOTAL TIME FOR A | | 0 | |
| B = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 2.1 | Chemistry – Level 1 | 13 | |
| 2.2 | Chemistry – Level 2 | 9 | |
| 2.3 | Chemistry – Level 3 | 6 | |
| 5.1 | Residues – Level 1 | 13 | |
| 5.2 | Residues – Level 2 | 8 | |
| 5.4 | Residues – Level 4 | 4 | ● |
| 6.1 | Occupational Health and Safety – Level 1 | 13 | |
| 6.2 | Occupational Health and Safety – Level 2 | 7 | |
| 6.3 | Occupational Health and Safety – Level 3 | 4 | ● |
| 9 | Non-food trade | 6 | |
| 10.1 | Special data – Level 1 | 13 | |
| 10.2 | Special data – Level 2 | 7 | |
| 10.3 | Special data – Level 3 | 7 | |
| TOTAL TIME FOR B | | 4 | |
| 2E = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 8.1 | Efficacy and safety – Level 1 | 6 | |
| 8.2 | Efficacy and safety – Level 2 | 4 | |
| 8.3 | Efficacy and safety – Level 3 | 3 | |
| TOTAL TIME FOR E | | 2 x 0 = 0 | |
| 3C = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 11.1 | Finalisation – type 1 | 3 | |
| 11.2 | Finalisation – type 2 | 2 | |
| 11.3 | Finalisation – type 3 | 2 | ● |
| TOTAL TIME FOR C | | 3 x 2 = 6 | |
| J = whichever is relevant | | | |
| | Consultation with jurisdictional coordinator | 3 | ● |
| | In any other case | 0 | |
| TOTAL TIME FOR J | | 3 | |
| D | TOTAL TIME FOR D | 4 | ● |
| X = whichever is relevant | | | |
| | Appointment of an arbitrator under s.64 | 3 | |
| | In any other case | 0 | ● |
| TOTAL TIME FOR X | | 0 | |
| TOTAL TIMEFRAME | | 17 months | |